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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,113	03/10/2004	Myron Spector	1194-176	2494

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EXAMINER
GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,113	SPECTOR ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on 3/10/04 is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/04,8/24/05,11/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-7, 9-15, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al.

The '278 patent discloses a single sheet of a resorbable sidewall material consisting essentially of a single layer collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, this sheet material further having a fibrous inner surface opposite the smooth barrier surface (column 1, line 51 to column 2, line 6) derived from

collagen membrane peritoneal tissue (column 2, lines 52-60). This single layer collagen sheet material is identified as Bio-Gide ® by the instant specification (page 3, paragraphs 0017 and 0018), thereby meeting the limitations of the instant claims. The '278 patent does not disclose a nerve regeneration tube for connecting nerve ends having an inner diameter of about 0.5-5mm and a length of about 10-100mm formed from the single collagen sheet of the '278 patent, or a filling material comprised of a mixture of Type I and Type IV collagen, or collagen fibers having a substantially longitudinal orientation with respect to said tube, or a filling material including laminin as a nerve growth stimulant. Shimizu discloses a nerve regeneration tube comprising of at least three sheets of collagen (column 6, line 48 to column 7, line 50) but which is also about 1-8mm in inner diameter with a length about 28-35mm, but can differ according to the length of the severed portion of the nerve and the thickness of the nerve (column 7, lines 19-31; see also a 10mm long tube in Comparative Example 4), thereby meeting the limitations of the instant claims. Shimizu also teaches filling materials for a nerve regeneration tube comprising laminin and Type IV collagen (column 8, lines 40-55) and collagen Type I solution or fibers having a substantially longitudinal orientation with respect to said tube (column 7, line 55 to column 8, line 13; column 8, line 65 to column 9, line 48). Shimizu does not explicitly disclose a reasonable expectation of success of making a collagen nerve regeneration tube out of a collagen sheet of membrane. Both Hentz et al. and Rosen et al. teach in their abstracts the feasibility and likelihood of success of making collagen tubes out of collagen sheets or membranes. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the

single sheet collagen material of the '278 patent to make a nerve regeneration tube out of collagen as taught by Shimizu because Shimizu employs at least three sheets of collagen to produce his nerve regeneration tube and by using a single sheet of collagen with the attractive features (one side smooth and inhibits cell permeation, the other side fibrous to promote biological regrowth) taught by the '278 patent, a simpler nerve regeneration tube can be produced that uses less material (single sheet as opposed to at least three sheets of collagen), is quicker and easier to produce, and would have the further advantage of economic savings due to lowered costs of production by reducing the need for at least three sheets of collagen to a single sheet of collagen. The combined references also establish a *prima facie* case of obviousness because the collagen material of the '278 patent has desirable features such as a smooth surface to inhibit cell adhesion on the outside with a fibrous surface to support cells on the inside and simply forming a tube out of this two-sided collagen material is *prima facie* obvious given that collagen nerve regeneration tubes were in use at least as way back as the 1980s, and the '278 patent collagen material is used as a single sheet to make a collagen nerve regeneration tube as opposed to at least three sheets of collagen which are used in the prior art of record. Finally, the advantageous characteristics of the two-sided collagen material of the '278 patent would suggest to and motivate the ordinary artisan to fashion the collagen material into a tube with a smooth outside and fibrous inside in order to promote axonal regeneration in the interior of the tube as indicated by Shimizu (column 7, line 55 to column 8, line 13; column 8, line 40 to column 9, line 63).

4. Claims 1-7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. as applied above and further in view of Stensaas et al. (US 4,778,467, "Stensaas"). None of Geistlich or Shimizu or Hentz et al. or Rosen et al. explicitly teach methods of forming tubes from collagen sheets, although Shimizu does teach a collagen nerve regeneration tube and Hentz et al. and Rosen et al. do describe making tubes from collagen sheets. Stensaas teaches methods of forming tubes for nerve regeneration (Figures 1 and 3A-3B, column 10, line 3 to column 11, line 5) with or without silicone rubber adhesive that meet the limitations of the instant claims (also see column 9, lines 1-16 and column 16, lines 54-66 (Figures 7A-7B) for overlapping edges). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the teachings of Stensaas to make various kinds of tubing (opposed edges, overlapping edges, etc.) out of a collagen sheet material because the other references, while teaching the desirability of doing so, lack explicit descriptions and drawings as to how to accomplish the actual construction of various types of tubes for nerve regeneration, which Stensaas does teach. The ordinary artisan, searching for information to fabricate nerve regeneration tubes, would find the teachings of Stensaas and find it *prima facie* obvious to use his disclosure in combination with the other references because Stensaas supplies the explicit teachings that the other references lack concerning nerve regeneration tube construction.

5. Claims 1-15, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. as applied above and further in view of Humes (US 5,429,938). None of Geistlich or Shimizu or Hentz et al. or Rosen et al. teach a mixture of Type I and Type IV collagen in a ratio of about 1:1 for supporting biological activity. Humes does teach the use of Type I and Type IV collagen in about 1:1 ratios to support biological activity (column 3, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ Humes' ratio of about 1:1 of Type I and Type IV collagen because the other references do not qualitatively teach specific amounts between Type I and Type IV collagen and the artisan would be motivated to look to the Humes reference to supply this missing information if said artisan was actually going to reduce to practice a combination of Type I and Type IV collagen because such information would be required during fabrication.

6. No claim is allowed.

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571) 273-8300.

Stephen Gucker

September 30, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER